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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,900	02/12/2002	Isabelle Arnould-Reguigne	ST01002 US NP	3572

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EXAMINER	
EMCH, GREGORY S	
ART UNIT	**PAPER NUMBER**
1649	

NOTIFICATION DATE	DELIVERY MODE
09/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/072,900	ARNOULD-REGUIGNE ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-9,12,13,16,17,22,41-43,47 and 51-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-9,12,13,16,17,22,41-43,47 and 51-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim 3 has been amended and claims 18-21 and 23-25 have been canceled as requested in the amendment filed on 11 July 2007. Following the amendment, claims 1, 3-5, 7-9, 12, 13, 16, 17, 22, 41-43, 47 and 51-63 are pending in the instant application.

Claims 1, 3-5, 7-9, 12, 13, 16, 17, 22, 41-43, 47 and 51-63 are under examination in the instant office action.

Claim Rejections - 35 USC § 101, 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 3-5, 7-9, 12, 13, 16, 17, 22, 41-43, 47 and 51-63 under 35 U.S.C. 101 is maintained for the reasons of record and as set forth below.

In the reply filed 11 July 2007, Applicants assert that the instant gene is mapped to the same chromosomal region of various diseases, including ichthyosis. Thus, Applicants conclude that the gene is a marker for those disorders. Applicants also assert that the instant application describes polymorphisms of the ABCA12 gene that

enables the artisan to identify different forms of the gene. Further, Applicants assert that there are discernable markers for ABCA12, and said markers can be used for diagnosing a disorder mapping to that same region or which is found to be linked to a polymorphism of ABCA12. Applicants assert that based on the teachings of the specification, the skilled artisan would decipher the utility of the claimed invention without the need for further research to determine if ABCA12 would be useful in diagnosing ichthyosis.

Applicants' arguments have been fully considered and are not found persuasive.

Contrary to Applicants' assertion, the instant specification is completely silent as to using ABCA12 to diagnose lamellar ichthyosis. Even though ABCA12 is associated with lamellar ichthyosis, Applicants have not explicitly taught that ABCA12 would be useful in the treatment of the disease or that assaying for ABCA12 mutations would be useful for diagnosing lamellar ichthyosis. Thus, further research would indeed be required to determine if and how ABCA12 and the instant variants would be useful in the treatment or diagnosis of such a disorder.

The prior art (post-filing date) confirms that ABCA12 is associated with lamellar ichthyosis; however, the specification neither teaches nor suggests the missense mutations as taught by the prior art.

The claims are directed to a genus of polynucleotides, whereas the evidence only indicates that certain sequences are associated with a specific disease. Further, this specific disease is not commensurate with the scope of the teachings in the specification, since the specification only refers to a relatively large chromosomal

location, which encompasses markers and loci for genes other than the one disclosed and may correlate with other genetic diseases, not only ichthyosis.

MPEP 2107.01 teaches, "Thus a 'substantial utility' defines a 'real world' use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a 'substantial utility' define a 'real world' context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a 'real world' context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use and, therefore, do not define 'substantial utilities':

> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
> (B) A method of treating an unspecified disease or condition;
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility."

The specification only asserts that the polynucleotide has utility in diagnosing disease *in general*, and not icthyosis *in particular*. The prior art evidences that further research was required after the filing date to reasonably confirm the real-world use, and

to identify the disease linked to the disclosed sequence. Thus, the asserted utility in disease diagnosis is not substantial and the instant rejection under 35 U.S.C. 101 is maintained.

The rejection of claims 1, 3-5, 7-9, 12, 13, 16, 17, 22, 41-43, 47 and 51-63 under 35 U.S.C. 112, first paragraph for lack of enablement is maintained for reasons of record and as set forth above. Specifically, since the claimed invention is not supported by either a specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Furthermore, assuming arguendo that claims 3-5, 41-43, 47 and 51 were enabled, as referred to previously; the claims would not be enabled for their full scope.

In the reply filed 11 July 2007, Applicants assert that they have amended claim 3 and dependent claims such that the claimed nucleic acid sequences have the percentage identity to SEQ ID NOs: 1-4 in the alternative, and encodes a protein that binds to ATP, contains a transmembrane domain and is an ABCA member. Thus, Applicants apparently consider the claims as not overbroad.

Applicants' arguments have been fully considered and are not found persuasive.

Applicants' amendment of claim 3 has not narrowed the scope of the claim and dependent claims therefrom. Said claims are still overly broad in the recitation of percent identity, hybridizing nucleic acids and functional limitations, since insufficient guidance is provided as to which of the myriad of nucleic acid species encompassed by

the claims will retain the characteristics of encoding proteins that bind ATP, comprise a transmembrane domain and are ABCA member(s). Further, the art does not provide compensatory teachings.

The rejection of claims 3-5, 41-43, 47 and 51 under 35 U.S.C. 112, first paragraph, for lack of written description is maintained for reasons of record and as set forth below.

In the reply filed 11 July 2007, Applicants assert that they have amended claim 3 and dependent claims such that the claimed nucleic acid sequences have the percentage identity to SEQ ID NOs: 1-4 in the alternative, and encode a protein that binds to ATP, contains a transmembrane domain and is an ABCA member. Thus, Applicants conclude that the instant rejection has been overcome.

Applicants' arguments have been fully considered and are not found persuasive.

Applicants argue that the specification contains an adequate written description of the claimed subject matter because the claims contain limitations, which require that the proteins are encoded by the gene, comprise a transmembrane domain and are ABCA member(s). However, the claimed nucleic acid sequences could encode polypeptides that vary greatly from that of ABCA12. Further, the specification does not teach the skilled artisan how to make derivatives of ABCA12 that have the same function as ABCA12. In addition, the specification does not provide a patentable utility or function for ABCA12.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the full-length sequences of SEQ ID NOs: 1-4, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the instant case, the specification does not provide a representative number of species to fulfill the written description requirement of 35 U.S.C. 112, first paragraph.

Therefore, one of skill in the art would not be able to predictably identify the encompassed molecules.

The new matter rejection of claims 5, 7, 9, 13, 16, 17, 47, and 51-63 under 35 U.S.C. 112, first paragraph is maintained for reasons of record and as set forth below. . The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the reply filed 11 July 2007, Applicants assert that the specification as filed does provide a written description for the claimed nucleic acids of 8, 9, 19, 27, 28 or 30 nucleotides, nucleic acids of at least 1000 or nucleic acids of at least 1500 nucleotides of any one of SEQ ID NOs: 1-4. Applicants allege that support for the claims containing said subject matter may be found on page 9, lines 23-25, which discloses that the inventions relates to a nucleic acid comprising at least 8 consecutive nucleotides of a nucleotide sequence of any one of SEQ ID NOs: 1-4 or complementary nucleotide sequence thereof and on page 56, Table 3, where specific SEQ ID NOs contain primers of SEQ ID NO: 1 consisting of consecutive nucleotides of lengths 19, 27 and 28. Hence, Applicants allege that the written description requirement has been satisfied.

Applicants' arguments have been fully considered and are only partially persuasive.

The Examiner concedes that the cited passages contemplate primers of 8 consecutive nucleotides of a nucleotide sequence of any one of SEQ ID NOs: 1-4 (p.9)

and primers of SEQ ID NO: 1 that consist of 19, 27 and 28 nucleotides (Table 3). However, the specification as-filed does not provide a written description for the claimed nucleic acids of 9 or 30 nucleotides of SEQ ID NO: 1, nucleic acids of 9, 19, 27, 28 or 30 nucleotides of SEQ ID NOs: 2-4, nucleic acids of at least 1000 or nucleic acids of at least 1500 nucleotides of any one of SEQ ID NOs: 1-4. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. 112.

Applicants are required to cancel the new matter in the response to this Office action.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

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Patent Examiner
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12 September 2007

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